REMARKS/ARGUMENTS

Reconsideration of the captioned application in view of the foregoing amendments and following Remarks is respectfully requested.

The claims were claims 1-19. By this Amendment, claims 1-6 have been canceled and replaced by new claims 20-36 and claims 7-19 directed to non-elected subject matter have been canceled. Support for new claims 20-41 can be found throughout the specification, for example, at page 5, line 6, page 7, lines 22-23 and page 10, lines 14-16. Accordingly, the claims under consideration are claims 20-36.

A petition to extend the time to respond to the pending Office Action by three months is filed concurrently herewith.

In the Office Action, restriction is required under 35 USC § 121 to one of the following:

I. Claims 1-6, drawn to a substrate coating.

II. Claims 7-14 drawn to a pharmaceutical composition.

III. Claims 15-19 drawn to a method of depositing a coating.

Applicants hereby affirm the provisional election to prosecute the subject matter of Group I. Applicants reserve the right to file applications directed to the canceled nonelected subject matter at the appropriate time.

Claim 1 is rejected under 35 USC § 112, second paragraph, as allegedly indefinite. This rejection is respectfully traversed.

In the Office Action under Reply it is stated that:

> The parentheses within the claim render it indefinite because it is unclear whether the limitations are part of the claims. Claim 1 also recites a film coating comprising or consisting essentially of polyethylene glycol with a particle size ranging from 1 to 100 microns. However, it is unclear how a film coating can comprise discrete particles.

Applicants respectfully submit that new claims 20-36 do not contain any parenthesis within the claims. Applicants respectfully submit that the particle size of the PEG is clear in that micronized PEG is a component of the substrate coating.

Accordingly, Applicants submit that new claims 20-36 meet the requirements of 35 USC § 112, second paragraph.

Thus, Applicants request that the rejection under section 112 be withdrawn.

Claims 1-3 and 6 are rejected under 35 USC § 102 as allegedly anticipated by Hogan et al. (WO 96/35413). This rejection is respectfully traversed.

It is asserted in the Office Action that:

> The Hogan et al. document teaches a substrate coating for the electrostatic deposition of active substances (see page 1, lines 4-18; page 3, lines 3-27; and page 5, line 33 to page 6, line 11). The coating material preferably has a melting point of 50°C to 180°C (see page 7, lines 10-15). This material, in its powder form, has a particle size of less than 50 microns (see page 8, lines 7-16); and in one preferred embodiment, the powdered material has a mean particle size of about 10 microns, and substantially no particles larger than 100 microns in diameter (see page 9, lines 29-31). Polyethylene glycol with molecular weights of 20,000 and 6,000 are used in the coating material (see example 1, page 31, lines 12-13; and Example 6, page 34, line 26). Additional components may be included in the coating material, including opacifiers, colorants, flavorants, and sweeteners (see page 18, lines 3-28).

Applicants submit that new claims 20-36 are not anticipated by Hogan et al.

New claim 20 recites a substrate coating for use in electrostatic dry deposition of a dry powder medicament on a negatively charged substrate wherein the coating comprises the dry powder medicament wherein the medicament when triboelectrically charged has a negative charge and micronized (PEG) with molecular weight in the range of 1,000 to 20,000 and having a particle size of 1-100 μm.

Applicants respectfully submit that Hogan et al. does not teach or suggest a coating for a negatively charged substrate comprising a negatively charged medicament (when triboelectrically charged) and PEG.

Thus, Applicants request that the rejection under § 102 be withdrawn.

Claims 1-6 are rejected under 35 USC § 103(a) as allegedly unpatentable over Hogan et al. either alone or taken in view of Sturzenegger et al. (U.S. Patent No. 4,197,289). This rejection is respectfully traversed.

In the Office Action, Sturzenegger is relied on for allegedly disclosing a polymeric formulation of an edible web which may include plasticizers and upon which a powdered medicament can be deposited.

Applicants respectfully submit that Sturzenegger nowhere discloses or suggests a coating for a negatively charged substrate comprising a negatively charged medicament and PEG.

Thus, Applicants submit that neither Hogan taken alone or in view of Sturzenegger et al. teach or suggest the claimed substrate coating.

Accordingly, Applicants request that the rejection under 35 USC § 103(a) be withdrawn.

Since the claims are of proper form and patentable over the cited art an allowance and notice thereof is respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made".

Respectfully submitted,

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Dated: December 3, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please cancel claims 1-6 and replace with new claims 20-36.

Please cancel claims 7-19.

Please add the following new claims:

-- 20. A substrate coating for use in electrostatic dry deposition of a dry powder medicament on a negatively charged substrate wherein the coating comprises the dry powder medicament wherein the medicament when triboelectrically charged has a negative charge and micronized (PEG) with molecular weight in the range of 1,000 to 20,000 and having a particle size of 1-100 μm.

21. The coating of claim 20 wherein the dry powder medicament is ethinyl estradiol.

22. The coating of claim 1 further comprising norgestimate.

23. The coating of claim 21 wherein the ethinyl estradiol is present in an amount in the range of from about 20 μg to about 50 μg.

24. The coating of claim 21 wherein the ethinyl estradiol is present in an amount in the range of from about 30 μg to about 40 μg.

25. The coating of claim 21 wherein the ethinyl estradiol is present in an amount of about 35 μg.

26. The coating of claim 21 wherein the ethinyl estradiol is micronized to a particle size in the range of from about 5 μm to about 20 μm.

27. The coating of claim 21 wherein the ethinyl estradiol is micronized to a particle size in the range of from about 5 μm to about 10 μm.

28. The coating of claim 22 wherein the norgestimate is present in an amount in the range of from about 30 μg to about 250 μg.

29. The coating of claim 22 wherein the norgestimate is micronized to a particle size in the range of from about 5 μm to about 20 μm.

30. The coating of claim 22 wherein the norgestimate is micronized to a particle size in the range of from about 5 μm to about 15 μm.

31. The coating of claim 20 wherein the polyethylene glycol is micronized to a particle size in the range of from about 5 μm to about 10 μm.

32. The coating of claim 20 wherein the polyethylene glycol has a molecular weight in the range of from about 6000 to about 8000.

33. The coating of claim 20 wherein the polyethylene glycol has a molecular weight of about 8000.

34. The coating of claim 20 wherein the polyethylene glycol has a molecular weight of about 6000.

35. The coating of claim 20 wherein the ratio of dry powder medicament to polyethylene glycol is from about 1:1 to about 1:60.

36. The coating of claim 20 wherein the ratio of dry powder medicament to polyethylene glycol is from about 1:1 to about 1:40. --